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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,606	12/27/2001	Hidemitsu Nishida	1110-0306P	9102

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EXAMINER

PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/026,606

Applicant(s)

NISHIDA ET AL.

Examiner

Sudhaker B. Patel, D.Sc.T ch.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 8.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims (in part) 1-5 drawn to compounds, composition, a method of use and the first recited process of making spiro-tricyclic Formula (I) wherein A is 6-membered heterocycle e.g. pyridine; B = a single bond; X = -CH₂-; Y = Oxygen; integers m = zero, l = 1 i.e. 5-membered 1,3-oxazin ring; Z = -CO-; T = SO₂; Q = phenyl or naphthalene, classified in class 514, subclass 249. If this group is elected further restriction/election will be required. Additionally a single species from working examples with all variables exactly and definitely defined must be disclosed.
 - II. Claims (in part) 6,7,9, drawn to compounds, composition, a method of use and the first recited process of making the spiro-bicyclic compounds of Formulae V, VI, I a', classified in class 546, subclasses various depending on the nature of A, B, X, Y, R variables and integers m, l. If this group is elected further restriction/election will be required. Additionally a single species from working examples with all variables exactly and definitely defined must be disclosed.

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- III. Claims (in part) 8,10,11,12, drawn to compounds of Formulae I_k, I_l, I_m, I_n, classified in class 544, subclasses various depending on the nature of various variables. . If this group is elected further restriction/election will be required. Additionally a single species from working examples with all variables exactly and definitely defined must be disclosed.

- IV. Claims (in part) 13,14,15,16, drawn to compounds, composition, a method of use, classified in class 514,562,564, subclass various depending on the nature of compounds of claim 13. . If this group is elected further restriction/election will be required. Additionally a single species from working examples with all variables exactly and definitely defined must be disclosed.

- V. Claims (in part) 17,18, drawn to method of use of a pharmacophore and other methods for identification or designing an inhibitor, classified in various classes and, subclasses depending on the nature of a pharmacophore or as an inhibitor. . If this group is elected further restriction/election will be required. Additionally a single species from working examples with all variables exactly and definitely defined must be disclosed.

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- VI. Claims (in part) 1-15, drawn to compounds, composition, a method of use which are not included in above inventions of groups I-V, classified in classes and, subclasses depending on the nature of substituents. . If this group is elected further restriction/election will be required. Additionally a single species from working examples with all variables exactly and definitely defined must be disclosed.

The inventions are distinct, each from the other because of the following reasons:

The groups as presented above, are distinct inventions, each from the other because of the following reasons: The compounds of Groups I-VI are drawn to:

- (1). Structurally diverse compounds that are made and used independently of each other;
- (2). Compounds are separately classified;
- (3). Classes will require separate literature searches;
- (4). Compounds are not art recognized equivalents, and additionally,
- (5). The groups lack unity of invention(see MPEP 803.02).

Based on above stated data i.e. (1) - (5)., claim 1 also lacks unity of invention.

2. Inventions I-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Compounds of WO 9616940 can be also used for the utility as claimed herein.

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3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-VI, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Claims 1-2,3-13, 17,18 are generic to a plurality of disclosed patentably distinct species comprising (where applicable) (1). A component having meanings H, Hydrocarbon, 5 or 6-membered heterocycle, -NH₂, imidoyl; (2). B = absent or forming a CO or S, So SO₂ or alkylene; (3). X is N or CH₂ i.e. forming cyclohexane or piperidine cores; (4). Integers m + l = 1 i.e. forming a 5-membered ring with Y (= O/S/SO/SO₂/NH) and N; (5). Integers m + l = 2 i.e. forming a 6-membered ring; (6). Integers m + n = 3 i.e. forming a 7-membered ring; (7). Integers m + n = 4 i.e. forming an 8-membered ring respectively. Additionally, the components T & Q will provide further many compounds, which are not chemical equivalents of each other. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. A telephone call was made to G. M. Murphy on 4/22/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is 703 308 4709. The examiner can normally be reached on 6:30 to 5:00 pm.Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr.Mukund J. Shah can be reached on 703 308 4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.



Sudhaker B. Patel, D.Sc. Tech.
September 10, 2003.



MUKUND SHAH
SUPERVISORY PATENT
EXAMINER
ART UNIT 1624